



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

sw

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,920	02/20/2002	Motasim Sirhan	020460-000230US	1180
20350	7590	07/27/2004	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR SAN FRANCISCO, CA 94111-3834			WEBB, SARAH K	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 07/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/080,920

Applicant(s)

SIRHAN ET AL.

Examiner

Sarah K Webb

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-166 is/are pending in the application.
- 4a) Of the above claim(s) 3-10, 24, 25, 33, 34, 50-68, 75, 77, 78, 86-90, 92-96, 101-106, 108-131, 145, 146, 156-166 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 11-23, 26-32, 35, 45-49, 69-74, 76, 79-85, 91, 97-101, 107, 132-144 and 147-155 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/1/02.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election Group I, species b of Figures 5A and 5B in the paper dated 6/24/04 is acknowledged. For clarification, only claims 108-131 and 156-159 are included in Group II. Applicant stated that claims 1-4, 11-32, 35-39, 45-49, 69-74, 76-85, 91, 97-101, 103, 105, 107, 132-155 read on the elected species. Examiner asserts that the claims readable on the device shown in Figures 5A and 5B include only 1, 2, 11-23, 26-32, 35, 45-49, 69-74, 76, 79-85, 91, 97-101, 107, 132-144, and 147-155. A stent, inflation tube, and a second balloon are NOT included in the species of Figures 5A and 5B. Further, the transverse ends of the groove have an opening between them in Figures 5A and 5B, so claims 77, 78, 145, and 146 do not read upon this election. Since claim 3 is not readable on the elected species, the multiple dependent claims should be amended to exclude claim 3.

Claim Objections

2. Claim 136 is objected to because of the following informalities: the word balloon is misspelled in line 2. Appropriate correction is required.
3. Claims 29-32 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.
4. Claims 14, 15, 19, and 83 are objected to under 37 CFR 1.75(c), as failing to further limit the subject matter of a previous claim. Applicant is required to cancel the

Art Unit: 3731

claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 14 and 15 do not further limit claim 13. The omission of "metal alloy" in claim 19 does not further limit claim 18. The numerical range of claim 83 is greater than the range of claim 82.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 12, 18-20, and 137 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 12, it is unclear what shape the catheter body should be.

Regarding claims 18 and 19, it is unclear from what material the catheter body should be formed.

Regarding claim 20: Claim 19 only states the material *may* be a metal, so the limitation in claim 20 directed toward a metal is improper. Applicant should first state that the material is a metal before reciting limitation directed toward the metal.

Regarding claim 137, the inflation lumen 29 in Figure 5B has a continuous boundary. The groove is formed along a surface of the guide wire/catheter lumen.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 3731

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1,2,11,12,16-19,22,23,26-28,35,46,47,49,69,70,91,97-100,107 are rejected under 35 U.S.C. 102(b) as being anticipated by US 4,655,746 to Daniels et al.

As best illustrated in cross section in Figure 3, a balloon catheter includes a catheter body (68) with a guide wire (74) positioned in a guide wire lumen (70) and a first balloon structure (16) that has a passage (18) that receives the catheter body (68). The catheter body (68) has a circular shape and a lumen (70). As shown in Figure 5, an atraumatic tip (76) is positioned at the distal end of the catheter (68) (column 4, lines 55-57). Regarding claim 17, the distal end (16b) of the balloon structure (16) is distally tapered and has multiple lumens (see Figure 4). The catheter body (68) is formed from a polyethylene, a polymer (column 4, line 50). Regarding claims 22 and 26, the balloon structure includes a shaft (16) with an inflatable balloon (30) on the distal end and an inflation lumen (24)(column 3, lines 39-41). The passage (18) of the balloon structure (16) extends both proximally and distally of the balloon (30). Daniels explains that the balloon structure includes a sleeve (32) with an inflatable portion (30)(column 3, lines 50-60).

7. Claims 132-136, 138,140-142,144,147-149,155 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,195,978 to Schiffer.

Schiffer discloses a balloon catheter (Figure 1) that includes an inflation lumen (28) and a passage (30) that slidably receives an elongate body (18) (column 6, lines 11-16). The passage (30) includes an axial groove that is capable of removably receiving the elongate body (18), as illustrated in Figure 3. As shown in Figures 4-6, the

Art Unit: 3731

groove has two transverse ends (34,36) when the strip (32) is removed. Regarding claims 147-149, the groove extends a majority of the length of the catheter body, which is 100 to 160 cm (column 8, line 68). Schiffer explains that part of the shaft may be formed as a metal hypotube (column 9, line 6) and the shaft (22) has sufficient stiffness and pushability (column 5, line 62).

8. Claims 132-136,138,143,144,155 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 5,395,335 to Jang.

Jang discloses a balloon catheter in Figure 3 that includes an inflation lumen (22), a passage (20) for slidably receiving an elongate body (50), or guide wire, and an axial groove (40) that removably receives the guide wire. The groove is formed as multiple intermittent grooves, or perforations.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 72, 73,76,79-81,101, and 154 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schiffer in view of Daniels.

Schiffer includes all the limitations of claims 72 and 73, except for a catheter also being received in the passage so that it surrounds the guide wire. Daniels teaches that a passage in a balloon catheter can be configured to receive a catheter with a guide wire receiving lumen. Since both devices are balloon catheters, it would have been

Art Unit: 3731

obvious to one of ordinary skill in the art at the time the invention was made to combine the devices of so that the passageway of Schiffer receives a catheter with a guide wire lumen, as taught by Daniels.

10. Claim 74 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schiffer in view of Daniels, as applied to claim 72 above, and further in view of Jang.

The modified Schiffer device includes all the limitations of claim 74, except for the groove being formed as multiple intermittent grooves. Jang teaches that a groove in the wall of a guide wire receiving lumen can be perforated. It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the groove of the modified Schiffer device as multiple intermittent grooves, as Jang teaches that perforation is an alternate form of a groove to continuous groove.

11. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Daniels in view of US Patent No. 6,007,517 to Anderson.

Regarding claim 45, Daniels gives the dimensions of the catheter body. The diameter of the catheter is 20-50 mils (column 4, line 37), which when converted to French (F), falls within the claimed range. The length is 40-140 mils (column 3, line 33). Daniels fails to state the guide wire lumen dimension. Anderson teaches that a guide wire lumen in a balloon structure should be about 0.5 to 1 mm (column 8, line 20). It would have been obvious to one of ordinary skill in the art at the time the invention was made to make the guide wire lumen of Daniels 0.5 to 1 mm in diameter, as Anderson teaches that this is a suitable dimension for guide wire lumens in balloon structure passageways.

Art Unit: 3731

12. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniels in view of US Patent No. 5,830,227 to Fischell et al.

Daniels includes all the limitations of Fischell, except for a tapered distal end on the catheter. Fischell discloses another balloon catheter with a guide wire. Fischell teaches that the distal tip of the catheter body should be distally tapered between 1 and 5 cm so that the catheter can follow the guide wire more easily (column 1, line 42 and column 4, line 65). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a tapered distal tip on the catheter of Daniels, as Fischell explains that this helps the catheter to follow the guide wire through tortuous paths.

13. Claims 21 and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniels in view of Schiffer.

Daniels includes all the limitations of claims 21 and 71, except for forming the catheter as multiple bodies connected together. Schiffer teaches that a catheter body can have another tubular member, such as a hypotube, coupled to the proximal end for stiffening purposes (column 9, lines 5-7). It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the catheter of Daniels as multiple connected bodies, as Schiffer teaches that this structure can add strength to the catheter body.

14. Claims 82-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schiffer in view of Daniels, as applied to claim 76 above, and in further view of US Patent No. 5,135,535 to Kramer.

Art Unit: 3731

Schiffer, as modified by Daniels above, includes all the limitations of claims 82-85, except for stating the transverse dimension of the groove. Kramer states that it is well known in the art of balloon catheters that guide wire diameters range from 0.008 to 0.035 inches (column 7, lines 28-30). It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the dimension of the groove within the ranges specified in claims 82-85 so that the opening is sufficiently wide enough for the guide wire to pass through during removal.

15. Claims 150-153 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schiffer in view of US Patent No. 5,135,535 to Kramer.

Schiffer includes all the limitations of claims 150-153, except for stating the transverse dimension of the groove. Kramer states that it is well known in the art of balloon catheters that guide wire diameters range from 0.008 to 0.035 inches (column 7, lines 28-30). It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the dimension of the groove within the ranges specified in claims 150-153 so that the opening is sufficiently wide enough for the guide wire to pass through during removal.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K Webb whose telephone number is (703) 605-1176. The examiner can normally be reached on Mon-Fri 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, McDermott or Shaver can be reached on (703) 308-0858. The fax phone


Art Unit: 3731

number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SKW
07/19/04

SKW


DAVID O. REIP
PRIMARY EXAMINER